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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/475,704

12/30/1999

SUSAN W. BARNETT

1631.002

6738

27476

7590

01/16/2009

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

01/16/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/475,704	BARNETT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JENNIFER PITRAK	1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9.10.24-40.42.43.49-60.63-66 and 68-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9.10.24-40.42.43.49-60.63-66 and 68-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____.   | 6) <input type="checkbox"/> Other: _____.                         |

## DETAILED ACTION

### *Remarks*

Claims 9, 10, 24-40, 42, 43, 49-60, 63-66, and 68-75 are pending and are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Priority*

The instant claims are afforded the priority date of 09/01/1999 for the reasons of record.

### *Claim Rejections - 35 USC § 103 - maintained*

Claims 9, 10, 24-29, 33, 39, 40, 42, 43, 49-52, 54-60, 63-66, and 68-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shiver, et al.** (WO98/34640, international publication date 08/13/1998; of record 06/12/2000 IDS), **Haas, et al.** (1996, Current Biology, v.6:315-24, on IDS dated 10/29/2000), **Persson, et al.** (1998, Biologicals, v.26:255-65), and **Novitsky, et al.** (1998, direct submission to GenBank, 12/03/1998, Accessions AF110965 and AF110967). This rejection is maintained for the reasons of record.

Claims 9, 10, 24-29, 33, 39, 40, 42, 43, 49-60, 63-66, and 68-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shiver, et al.**, **Haas, et al.**, **Novitsky, et al.**, and **Persson, et al.**, as applied to claims 9, 10, 24-29, 33, 39, 40, 42-52, 54-60, 63-66, and 68-75

above, and further in view of **March, *et al.*** (1998, U.S. Patent 5,797,870). This rejection is maintained for the reasons of record.

Claims 9, 10, 24-40, 42, 43, 49-52, 54-60, 63-66, and 68-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shiver, *et al.*, Haas, *et al.*, Novitsky, *et al.*, and Persson, *et al.***, as applied to claims 9, 10, 24-29, 33, 39, 40, 42-52, 54-60, 63-66, and 68-75 above, and further in view of **Kapitonov, *et al.*** (2001, U.S. Patent 6,280,989, filed 06/17/1999). This rejection is maintained for the reasons of record.

### **Response to arguments**

Pertaining to all three rejections stated above, Applicant argues that the cited references do not teach or suggest the claimed sequences and that none of the cited references alone or in combination provides any reason, teaching, or suggestion to remove the INS sequences from a wild-type gag coding sequence, particularly because Shiver does not teach or suggest removing INS sequences, but rather, Shiver teaches checking the newly created sequence for "inadvertently" created sequences such as intron splice recognition sites and unwanted restriction enzyme sites. This is not persuasive. Shiver teaches removing "ATTTA" sequences generated by the codon replacements made to the wild type gene sequence. Although, as Applicant states, Shiver suggests inspecting the modified sequence for "ATTTA" sequences and substituting codons to eliminate such sequences, this does not preclude that it would have been obvious to one of skill in the art to do the same for any "ATTTA" sequences, wild-type or modified. Shiver's reference to "ATTTA" sites as inhibitory sequences demonstrates the knowledge of

those of skill at the time of the instant invention, that it was clearly known that “ATTTA” sequences are inhibitory and should be eliminated for efficient HIV protein expression. This is further evidenced by Schneider, et al. (1997, J. Virol., v.71:7892-903, item CA on 06/12/2000 IDS), which teaches that it was well known that wild-type “ATTTA” sequences can be eliminated by codon replacement (p.4895, second paragraph).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak  
Examiner  
Art Unit 1635

/Tracy Vivlemore/  
Primary Examiner, Art Unit 1635